REMARKS

Status of the Claims

Claims 1 – 34 are canceled. Claims 35 – 57 are pending. No claims have been withdrawn from consideration.

Claim Amendments

The claim amendments are made without prejudice, and without disclaimer of the canceled and/or modified subject matter. Indeed, "[t]he language in the … claims may not capture every nuance of the invention or describe with complete precision the range of its novelty."[1] Thus, "[t]he scope of [the present claims] is not limited to [their] literal terms but instead embraces all equivalents to the claims described."[2]

New independent claims 35, 55, and 57 finds support throughout the specification. Page 5, lines 1 – 9 provides general support. Page 7, lines 26 – 29 supports component b). Page 5, line 29 supports the weight percentage range of component c1). Page 6, line 43 supports the weight percentage range of component c2). Page 7, line 22 supports the weight percentage range of component c3). Page 7, lines 19 and 11 supports the clause of claim 35. Page 3, lines 17 – 21 supports the wherein clause of claim 57.

New claim 36 finds support in table 12.

New claim 37 finds support in table 5.

New claim 38 finds support on page 6, line 12.

New claim 39 finds support on page 7, line 32.

New claim 40 and 41 find support on page 5, lines 16 – 27.

New claims 42 – 44 find support on page 6, lines 32 – 41.

New claims 45 – 47 find support on page 7, lines 10 – 20.

New claim 48 finds support on page 8, lines 35 – 37.

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[1] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 731, 122 S.Ct. 1831, 1837 (2002).

[2] *Festo*, 535 U.S. at 731, 122 S.Ct. at 1837.

New claim 49 finds support on page 8, line 45 – page 9, line 20.

New claim 50 finds support on page 7, lines 36 – 37.

New claim 51 finds support on page 7, lines 39 – 40.

New claim 52 finds support on page 8, lines 1 – 5.

New claim 53 finds support on page 8, lines 3 – 5.

New claim 54 finds support on page 10, lines 7 – 20.

New claim 56 finds support on page 6, lines 36 – 37, and examples 2 – 4.

As discussed below, the claim amendments put the application in clear condition for allowance.

Amendments to the Specification

The abstract of U.S. 5,490,990 has been added to the sentence "Combinations of this type are described in US patent 5,490,990." This amendment does not add new matter. The specification need not disclose what is already available to the public. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

Claim Rejections

I. Claims 1, 4, 7 – 12, 14, 16 – 18, 22, 24, and 31 – 33 stand rejected in view of 35 U.S.C. §102(b), and US 4,837,032 to Ortega (hereinafter, "Ortega").

Ortega discloses a pharmaceutical tablet comprising:

A) 43 – 50 weight percent theophylline;

B) 10 – 20 weight percent water insoluble polymer, which according to column 3, lines 28 – 38 includes:

- polyvinyl acetate;
- polyvinyl alcohol;

- vinyl chloride/vinyl acetate copolymers;
- acrylate polymers and copolymers;
- methacrylate polymers and copolymers;
- copolymers of ethyl methacrylate; and
- copolymers of methyl methacrylate

C) 10 – 15 weight percent water soluble polymers or hydrophilic gel formers which swell in water, which according to column 3, lines 49 – 55 include:

- polyvinylpyrrolidene; and
- cellulose derivatives, including
  - hydroxyl propyl methyl cellulose,
  - methyl cellulose, and
  - sodium carboxy methyl cellulose

D) 5 – 15 weight percent acid insoluble polymer having carboxylic groups, which according to column 3, lines 39 – 48, include

- cellulose acetate phthalate,
- hydroxyl propyl methyl cellulose phthalate,
- esters of acrylic acid copolymers, and
- esters of methacrylic acid copolymers; and

E) optionally 5 – 9 percent hydrophobic lubricant, which according to column 3, lines 56 – 63 includes stearic acid.

Claim 10 of Ortega is directed to a pharmaceutical tablet comprising

A) 50 weight percent theophyline;
B) 15 weight percent polyvinylacetate (as the water insoluble polymer);
C) 15 weight percent polyvinyl pyrrolidone (as the water soluble polymers or hydrophilic gel formers which swell in water);
D) 15 weight percent cellulose acetate phthalate (acid insoluble polymer having carboxylic groups); and
E) 5 weight percent lubricant.

New claim 35 is not anticipated by Ortega, because the claim includes the

limitation, wherein the lipophilic additive, if present, is not stearic acid or cellulose acetate phthalate.

New claim 55 is not anticipated by Ortega, because the claim requires the oral dosage form to comprise from 1 to 40%, based on the total weight of the dosage form, of a water-soluble swelling polymer. According page 6, lines 32 – 41 of the specification as filed, the water-soluble swelling polymers which can be employed are: alginates, pectins, galactomannans, carrageenans, dextran, curdlan, pullulan, gellan, chitin, gelatin, xanthans, hemicelluloses, cellulose derivatives such as methylcellulose, hydroxypropylmethylcellulose, hydroxypropylcellulose, hydroxyethylcellulose, methylhydroxyethylcellulose, carboxymethylcellulose, starch derivatives such as carboxymethylstarch, degraded starch, polyacrylic acid copolymers. Possible salts of these substances are likewise included. Applicants respectfully note, at column 3, lines 49 – 53, Ortega states, "[t]he water soluble polymer or gel forming polymer which swells in water may be polyvinylpyrrolidone, or cellulose derivatives such as hydroxypropyl methyl cellulose, methyl cellulose, or sodium carboxy methyl cellulose." However, Ortega does not indicate that multiple water soluble polymers or gel forming polymers can be employed. Thus, a combination of polyvinylpyrrolidone and hydroxypropyl methyl cellulose is not anticipated by Ortega.

New claim 57 is not anticipated by Ortega, because the claim includes the limitation, wherein the formulated mixture is prepared by spray-drying a dispersion comprising polyvinyl acetate and polyvinylpyrrolidone.

II. Claims 1, 3 – 14, 16 – 18, 22 – 24, and 27 – 38 stand rejected in view of 35 U.S.C. §103(a), US 6,066,334 to Kolter et al. (hereinafter, "Kolter"), and Ortega.

As expressed by the U.S. Supreme Court, "[t]he rationale to support a conclusion that the claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded

nothing more than predictable results to one of ordinary skill in the art."[3] Furthermore, "[t]he determination of obviousness is made with respect to the subject matter as a whole, not separate pieces of the claim."[4]

Kolter describes uses for redispersible polymer powders or polymer granules consisting of:

A) 10 – 95 weight percent polyvinyl acetate;

B) 5 – 90 weight percent N-vinylpyrrolidone-containing polymer;

C) 0 – 20 weight percent of another water-soluble or water-swellable substance;

D) 0 – 20 weight percent water-insoluble dusting agent; and

E) optionally other additives.

At column 3, lines 38 – 44, Kolter explains the water-soluble or water-swellable protective colloids include cellulose derivatives, preferably hydroxypropylmethylcellulose, methylcellulose or hydroxyethylcellulose, galactomannan, pectin, xanthan, polyvinylalcohol, acrylate/methacrylate copolymers, sodium carboxymethyl starch, cellulose, degraded starches, maltodextrins etc.

Kolter describes using redispersible polymer powders or polymer granules as binders for producing solid pharmaceutical presentations where the binder content in the presentation is from 0.5 to 20% by weight. The Office action asserts it would have been obvious to increase the amount of binder based on the teachings of Ortega, with the expectation that doing so would delay the release of active ingredient.

Applicants respectfully submit, however, that upon making the proposed combination unexpected results would have been achieved. As exemplified in Tables 4 and 6 a more than additive, i.e., a synergistic result was obtained. These tables summarize results obtained when hydroxypropylmethylcellulose is employed as component c) of the present invention, and demonstrate the non-obviousness of the claimed invention, because "[a] greater than expected result is an evidentiary factor

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[3] MPEP §2143, citing *KSR*, 550 U.S. at ___, 82 USPQ2d at 1395; *Sakraida v. AG Pro, Inc.*, 425 U.S. 273, 282, 189 USPQ 449, 453 (1976); *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 62-63, 163 USPQ 673, 675 (1969); *Great Atlantic & P. Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 152, 87 USPQ 303, 306 (1950) (emphasis added).

[4] *Sanofi-Synthelabo, Inc. v. Apotex, Inc.* Fed. Cir. 2007-1438 (2008), citing KSR Int'l Co. v. Teleflex, Inc. 127 S.Ct. 1727, 1734 (2007); and *Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1448 (Fed. Cir. 1984).

pertinent to the legal conclusion of obviousness ... of the claims at issue."[5]

The unexpectedness of these synergistic results is emphasized upon comparison with column 4, lines 14 – 32 of Kolter, which states,

> It is furthermore possible for the products to contain other hydrophilic, water-soluble polymers such as polyvinyl alcohol, hydroxypropylmethylcellulose, hydroxypropylcellulose, methylcellulose, hydroxyethylcellulose, galactomannan, pectin, xanthan, acrylate/methacrylate copolymers, sodium carboxymethyl starch or – cellulose, degraded starches, maltodextrins or else low molecular weight substances such as monosaccharides, disaccharides, sugar alcohols, water-soluble inorganic salsts, amino acids, water-soluble acids and their salts or surfactants. These hydrophilic ancillary substances can also be added after the redispersion of a product consisting of polyvinyl acetate and polyvinylpyrrolidone or vinyl acetate/vinylpyrrolidone copolymers to give the binder dispersion. These hydrophilic ancillary substances may exert an additional stabilizing effect on the polyvinyl acetate dispersions and promote rapid release of the active ingredient from the presentation. The use of polyvinyl alcohol and methylhydroxypropylcellulose is particularly preferred.

Page 6, lines 5 – 11 of the present specification explains, "[i]t is probable that an interaction of the water-soluble polymer with a formulated mixture of the polymers polyvinyl acetate and polyvinylpyrrolidone leads to the very stable and reproducible release which is independent of the pressure for compression. The hardness of the tablets and the friability also show excellent values, which are often in fact better than without admixture of water-soluble polymers." Moreover, page 6, lines 16 – 19 of the specification explain, "Water-soluble but swelling, high-viscosity polymers surprisingly lead to slower release. It would have been expected that the inert matrix would be destroyed by the swelling polymer, and the active ingredient would be released more rapidly." However, on page 6, lines 25 – 27, the specification explains, "[t]he slowing of release is often greater than through the two components on their own. A synergistic effect is present."

Applicants respectfully submit that a greater than expected result has been demonstrated. Since the claimed combination yielded more than predictable results to

[5] MPEP §716.02(a), citing *In re Corkill*, 711 F.2d 1496, 226 USPQ 1005 (Fed. Cir. 1985).

one of ordinary skill in the art, the claimed invention is not obvious. Favorable reconsideration is respectfully requested.

III. Claims 1, 3 – 14, 16 – 13, 22 – 24, and 27 – 33 stand rejected in view of 35 U.S.C. §103(a), Kolter, Ortega, and US 4,816,259 to Matthews et al. (hereinafter, "Matthews").

Matthews is not cited to compensate for the shortcomings identified and discussed above, regarding the combination of Kolter and Ortega.

Fee Authorization

Please charge any shortage in fees due in connection with the filing of this paper, including any shortage in Extension of Time fees, to Deposit Account 14.1437. Please credit any excess fees to such account.

Conclusion

The present application is in condition for allowance, and applicants respectfully request favorable action. In order to facilitate the resolution of any questions, the Examiner is welcome to contact the undersigned by phone.

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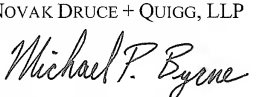

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